

HHS Action Plan to Prevent Healthcare-Associated Infections: INCENTIVES AND OVERSIGHT

I. Introduction

The Department of Health and Human Services (HHS), specifically the Centers for Medicare and Medicaid Services (CMS), has a variety of tools within its statutory and regulatory authority to encourage the prevention of healthcare-associated infections (HAIs). These tools can be broadly classified as regulatory oversight, financial incentives, transparency and associated incentives, or some combination of these. CMS also has a number of initiatives within each of these broad categories to combat healthcare-associated infections, and the following describes the various ways in which these tools and initiatives support the nation's efforts to prevent infections.

II. Regulatory Oversight

A. Introduction

The Conditions of Participation (CoPs) are the federal health and safety requirements that hospitals and other providers must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to ensure that high quality care is provided to all patients. Compliance with the CoPs is determined by State Survey Agencies (SAs) or Accreditation Organizations (AOs). The SAs survey hospitals to assess compliance with the CoPs. Hospitals are deemed to have met the requirements in the CoPs if they are accredited by national accreditation programs approved by CMS. All Medicare- and Medicaid-participating hospitals are required to be in compliance with CMS' CoPs regardless of their accreditation status.

B. Conditions of Participation

The Medicare CoPs are intended to be the minimum health and safety standards required for the protection of patients, and revisions to the CoPs require an extensive, (and, at times, lengthy) rulemaking process by CMS. When revisions are made to these requirements, particular attention must be paid to the ever-evolving nature of medicine and patient care. Moreover, a certain degree of latitude must be left in the requirements to allow for innovations in medical practice that improve the quality of care and move toward the reduction of medical errors and patient harm. These innovations in patient care, if supported by well-documented research evidence, most often lead to the issuance of guidelines and recommendations (sometimes referred to as "best practices"). These guidelines and recommendations come from federal agencies, such as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administrations (OSHA) within the Department of Labor, as well as from other

nationally recognized organizations. Historically, these national federal and private entities have been able to disseminate and update these best practices more quickly than CMS has been able to through its regulatory rulemaking process.

The hospital infection control CoP directly addresses the reduction of HAIs. Rather than continually revising the infection control requirements in the CoPs to meet emerging needs, the CoP is most effective serving used as a baseline requirement for hospitals. This COP baseline should be used by health systems to integrate nationally-recognized infection control standards and best practices into their individual infection control programs and to change their policies and procedures if, and when, the guidelines change.

Additionally, the CMS survey and certification interpretive guidelines for the Infection Control CoP (discussed in detail in Section II.D), provide a regulatory vehicle for a more specific discussion of best practices in infection control for hospitals. The current Infection Control interpretive guidelines contain references to the recommendations of organizations such as the CDC, OSHA, and the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, and the Association of Peri-Operative Registered Nurses. The guidelines specifically address special challenges to a hospital's infection control program, including multi-drug resistant organisms, communicable disease outbreaks, and bioterrorism, and directly refer to current and nationally accepted sources of information for hospitals on these challenges.

C. Accreditation

As mentioned above, accreditation by a nationally-recognized accreditation program can substitute for an ongoing State review. If a provider entity demonstrates through accreditation by an approved national Accreditation Organization (AO) that all applicable Medicare conditions are met or exceeded, CMS may "deem" those provider entities as having met the Medicare requirements. Accreditation by an AO is voluntary and is not required for Medicare participation. The use of private accreditation for ensuring provider compliance with Medicare requirements began in 1965 when Congress granted statutory deemed status for hospitals accredited by The Joint Commission. The statute was later amended to permit deeming for accreditation by national organizations other than The Joint Commission and for categories of providers beyond hospitals. A national AO applying for approval of deeming authority must provide CMS with a reasonable assurance that the AO requires accredited provider entities to meet requirements that are at least as stringent as the Medicare CoPs.

In addition to The Joint Commission's hospital program, hospitals currently have two other accreditation options. CMS has granted hospital deeming authority to the American Osteopathic Association (AOA) and Det Norske Veritas Healthcare (DNVHC). Specifics on each include:

- 1) AOA has had CMS approved hospital deeming authority since 1966 and is approved through September 25, 2009. CMS recently approved DNVHC's application for recognition as a national accreditation program for hospitals, effective September 26, 2008 through September 26, 2012.
- 2) DNVHC's hospital accreditation program is unique in that it integrates the ISO 9001 standards (international quality standards that define minimum requirements for a quality management system) and the Medicare CoPs. In addition, the program conducts annual, rather than triennial, surveys to ensure ongoing compliance.

Currently, there are approximately 4,072 Joint Commission-accredited hospitals, which is 83 percent of all hospitals (4,921) participating in the Medicare program. There are approximately 157 AOA-accredited hospitals; approximately half of these hospitals are dually-accredited by the Joint Commission and AOA. In total, over 84% (4,146) of all Medicare-participating hospitals are deemed by these AOs. Hospitals accredited by CMS-recognized AOs, are not subject to routine Medicare surveys by SAs. However, these hospitals are subject to validation surveys conducted by SAs on behalf of CMS in response to allegations of significant deficiencies which, if substantiated, would adversely affect the health and safety of patients.

Recently, Section 125 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) removed The Joint Commission's statutorily-guaranteed accreditation authority for hospitals, to be effective July 15, 2010. At that time, The Joint Commission's hospital accreditation program will be subject to CMS requirements for AOs seeking deeming authority. To avoid a lapse in deeming authority, The Joint Commission must submit an application for hospital deeming authority consistent with these requirements and within a time frame that will enable CMS to review and evaluate their submission.

D. Survey and Certification

The survey and certification program is designed to ensure that providers and suppliers comply with CoPs. CMS works with the SAs to conduct on site facility inspections for the vast majority of facilities that seek Medicare participation. Only certified providers, suppliers, and laboratories are eligible for Medicare or Medicaid payments. Currently, the CMS Survey & Certification Group oversees compliance with Medicare health and safety standards for more than 271,000 medical facilities of different types, including hospitals, laboratories, nursing homes, home health agencies, hospices, and end stage renal disease facilities. There are approximately 7,200 active SA surveyors nationwide (about 6,500 full-time equivalents), with roughly 500 dedicated to hospital surveys.

In FY 2008, CMS successfully trained more than 70% of the hospital surveyors on the new revised hospital interpretive guidelines for infection control (revised

November 21, 2007.¹ The interpretive guidelines are sub-regulatory, or a manual version of how CMS, through the SA surveyors, enforces regulatory requirements, including those associated with infection control. This November 2007 revision to the hospital interpretive guidelines for infection control was updated to reflect changing infectious and communicable disease threats as well as current and nationally-recognized infection control guidelines, best practices, and other resources for hospitals.

When deficiency findings, such as deficient infection control practices, are identified through a hospital or other setting survey, the information is captured in a database. In FY 2007, an infection control deficiency was cited 1% of the time on average. The database has several deficiency identifiers or tags that are related to infection control. With the use of specific tag identifiers for the deficient practice(s), CMS can later analyze the findings for greater insight into problem areas. For example, CMS is able to breakdown the CoP for infection control into subparta to specifically capture in our database whether the hospital is in compliance with having the required designated infection control officer (which “crosswalks” directly in CMS’s database to A-748).

Hospital complaints have typically been the second highest volume of complaints CMS receives among all the Medicare provider types certified. When the top allegations for complaints are examined, infection control issues are consistently in the top 12 (see Appendix D).

E. Recommendations and Action Plans

Conditions of Participation

The Medicare Hospital Infection Control CoP was first published over 20 years ago. Since then, infections such as HIV/AIDS, SARS, West Nile virus, avian influenza, and MRSA (to name but a few) have emerged and have been quickly followed by infection control guidelines. These tend to be specific to each emerging infection and are issued by nationally recognized organizations. The national organizations have typically revised the guidelines as needed to keep pace with new developments and as a way to help hospitals continue to track, monitor, and prevent such diseases.

However, as new sources of infection and communicable disease present new challenges to patient care, Medicare infection control requirements need to remain flexible and broad enough in their scope so that hospitals are able to incorporate the most current infection prevention and control guidelines into their programs. Shifting toward a more prescriptive regulatory approach (i.e., one that would focus on the prevention and control of specific infections and communicable diseases as would need to be designated in the regulatory text) would be a move backward to a more rigid and process-oriented regulatory structure. It would also be a move away from the more flexible and evidence-based approach that continues to prove a more successful model for reducing harm and improving outcomes for patients. Currently,

¹ www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=2&sortOrder=descending&itemID=CMS1205726&intNumPerPage=10

the Infection Control interpretive guidelines make direct reference to the evidence-based infection control guidelines and recommendations established by nationally-recognized organizations.

The following recommendations would further strengthen the commitment to quality in the prevention of HAIs:

- Require that a hospital ensure that their infection control program follows currently recognized standards of practice as established by national organizations.
- Require that the infection control program be an integral part of the hospital's quality assessment and performance improvement (QAPI) program. While the current Infection Control CoP does require that the hospital-wide quality assurance program address the problems identified by the infection control officer, this revision would more directly link the Infection Control CoP with the equally important QAPI CoP and would require hospitals to pursue a more proactive and innovative approach to infection control through their ongoing QAPI program.

Accreditation

In July 2004, the Government Accountability Office (GAO) made several recommendations to improve CMS oversight of the hospital accreditation program.² The recommendations included modifying the method used to calculate the disparity rate, identifying additional indicators of The Joint Commission's performance, and increasing the validation sample size. CMS' current and planned actions to enhance oversight of hospital accreditation are described below:

- Methodological Changes to Improve Oversight – CMS is assessing differing approaches to refining and improving the current method of measuring AO performance in assuring compliance with the CoPs. CMS secured the services of a contractor in FY 2006 to assist in this endeavor, which is expected to be expanded to address all AOs and all deemed programs. However, a revised approach to performance assessment may also require regulatory revisions.
- Analysis of Complaint Data – CMS is investigating cost-effective approaches to enhancing hospital survey activities, including integration into our overall assessment of the AO's performance, as a result of complaint investigations conducted in hospitals. CMS continues to work with a contractor to explore the utility of the complaint data as a means to assess the performance of the AOs.

Survey and Certification

In the survey and certification area, CMS and experts have identified a number of future enhancements for regulatory oversight of hospitals as recommendations:

² GAO-04-850, *CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals*

- Increase hospital surveyor training on recent revisions of hospital interpretative guidelines to ensure that 100% of dedicated hospital surveyors have the opportunity to be trained on the revised guidelines.
- Incorporate enhancements, which arise from collaborative activities with the CDC, into the surveyor training program as a means of providing surveyors with illustrative examples of best infection control practices in hospitals.
- Conduct a pilot of a surveyor tool. Piloting of a modified version of a CDC-developed surveyor tool for comprehensively assessing infection control practices in ambulatory surgical centers has begun. Depending on the assessment of the pilot experience, CMS may develop another version of the tool that could be employed in the hospital setting. This would require partnership with CDC for applicability to hospital setting.
- Consider instructing surveyors to assess compliance with infection control practices on every hospital complaint survey, in addition to assessing compliance with requirements related to the complaint allegation.
- Consider requiring AOs to also make assessment of infection control a priority focus.
- Partner with the AOs on sharing complaints or survey findings where infectious disease findings occurred.
- Consider joint educational intervention, such as a conference, with the AOs on the subject of infection control compliance. (Note this might be subject to privacy provisions and not be easily implemented.)
- Consider strengthening the relevant sections of the CoPs related to infection control and quality assurance/performance improvement.
- Consider adding a performance/evaluative metric related to hospital acquired infections. This could be accomplished in collaboration with CDC and AHRQ and using systems such as CDC's National Healthcare Safety Network (NHSN).

III. Value Based Purchasing (VBP) Financial Incentives

A. Introduction

CMS is applying the tools within its statutory authority to enhance the quality and efficiency of services provided to Medicare beneficiaries through value-based purchasing (VBP) and related initiatives. These include measurement and payment incentives to encourage beneficial interventions and outcomes to improve

performance. Using these resources, CMS is working to transform Medicare from a “passive payer” to a more active purchaser of higher value health care services.

The Preventable Hospital-acquired Conditions (HAC) Provision, and Present on Admission Indicator Reporting, and Hospital Pay-for-Reporting are three hospital-related initiatives that CMS is using to promote increased quality and efficiency of care.

In addition, CMS is studying the application of measurement and payment incentives to hospitals through various demonstration projects, and CMS has presented an approach to transition from pay-for-reporting to performance-based payment in the Hospital Value-Based Purchasing Plan Report to Congress. Each of these initiatives is discussed in turn below.

B. Hospital-Acquired Conditions and Present on Admission Indicator Reporting

Introduction

The HAC provision is one approach that CMS is using to combat healthcare-associated complications, including infections, in the hospital setting. The Medicare statute requires CMS to select conditions that will no longer trigger higher payment when they are acquired during hospitalization.

CMS selected conditions must be: (1) high cost, high volume, or both; (2) assigned to a higher paying Medicare-severity diagnosis-related group (MS-DRG) when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying MS-DRG if a selected condition is listed on the claim and was not present on admission. That is, the case will be paid as though the condition were not present. Medicare will continue to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission. However, if any non-selected complicating condition appears on the claim, the claim will continue to be paid at the higher MS-DRG rate.

CMS has also begun collecting a present on admission (POA) indicator to determine whether diagnoses were present on admission or acquired during hospitalization. On October 1, 2007, CMS began requiring hospitals to submit this information on Medicare claims. The POA indicator is necessary to identify which conditions are HACs for payment purposes, and this information is also potentially valuable for the broader public health uses of Medicare data.

Inpatient Proposed Payment System Payment Incentives

Medicare’s Inpatient Proposed Payment System (IPPS) encourages hospitals to treat patients efficiently. Hospitals generally receive the same payment for stays that vary

in the patient’s length of stay and in the intensity of the services provided, which gives hospitals an incentive to avoid unnecessary costs in the delivery of care. In some cases, complications, including infections, acquired in the hospital do not generate higher payments than the hospitals would otherwise receive for uncomplicated cases paid under the same DRG. To this extent, the IPPS encourages hospitals to avoid complications, including infections.

However, complications acquired in the hospital can generate higher Medicare payments. For instance, under the MS-DRGs that took effect for hospital payment in FY 2008, there are currently 258 sets of MS-DRGs that split into two or three subgroups based on the presence or absence of a complicating condition (CC) or major complicating condition (MCC).

If a condition is one of the conditions on the CC or MCC list, the hospital receives a higher MS-DRG payment, unless CMS selected the condition as an HAC and the condition was not present on admission. Medicare continues to assign a discharge to a higher paying MS-DRG if the selected condition is present on admission.

The following table demonstrates how payments are made on average depending on the MS-DRG assignment and the POA Status of a single secondary diagnosis:

| MS-DRG Assignment (Examples for a single secondary diagnosis) | POA Status of Secondary Diagnosis | Average Payment |
|--|--|----------------------------|
| Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke without CC/MCC | -- | \$5,347.98 |
| Principal Diagnosis: MS-DRG 065 <ul style="list-style-type: none"> ▪ Stroke with CC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Injury due to a fall (code 836.4 (CC)) | Y | \$6,177.43 |
| Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke with CC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Injury due to a fall (code 836.4 (CC)) | N | \$5,347.98 |
| Principal Diagnosis: MS-DRG 064 <ul style="list-style-type: none"> ▪ Stroke with MCC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Stage III pressure ulcer (code 707.23 (MCC)) | Y | \$8,030.28 |
| Principal Diagnosis: MS-DRG 066 <ul style="list-style-type: none"> ▪ Stroke with MCC Example Secondary Diagnosis: <ul style="list-style-type: none"> ▪ Stage III pressure ulcer (code 707.23 (MCC)) | N | \$5,347.98 |

This example illustrates the different MS-DRG payments that result when selected HACs are present on the claim. These scenarios are for a single secondary diagnosis only, which is atypical for a hospitalized Medicare beneficiary. The presence of at least one non-HAC CC/MCC on the claim will continue to trigger the higher paying MS-DRG.

Collaboration and Public Input in HAC Selection

CMS clinical quality experts have worked closely with public health and infectious disease experts from the CDC to identify the candidate preventable HACs, review comments, and select HACs. CMS and CDC staff also collaborated on the process for hospitals to submit a POA indicator for each diagnosis listed on inpatient Medicare claims and on defining the payment implications of the various POA reporting options.

On December 17, 2007, CMS and CDC hosted a jointly-sponsored HAC and POA Listening Session to receive individual input from the over 500 interested organizations and individuals who participated. CMS and CDC received verbal comments during the listening session and subsequently received numerous written comments. CMS has also sought public comment during FY 2007, FY 2008, and FY 2009 IPPS rulemaking. CMS noted that it will be considering additional HAC candidates, including additional infectious conditions, in future rulemaking. CMS expects to continue its collaboration with the CDC, other federal agencies, and stakeholders in the refinement and expansion of the HAC payment provision. As a next step, CMS and CDC intend to jointly sponsor a second HAC and POA Listening Session in December 2008.

HAC Selection Criteria

In selecting proposed candidate conditions and finalizing conditions as HACs, CMS and CDC staff evaluated each condition against the statutory criteria. These criteria limit which conditions can be selected for the HAC payment provision. The first criterion requires that a selected condition is high cost, high volume, or both. The second criterion requires that a selected condition trigger a higher Medicare payment. To do so, a condition must be represented by an ICD-9-CM diagnosis code that clearly identifies that condition, is designated as a CC or an MCC, and results in the assignment of the case to a higher paying MS-DRG when the code is reported as a secondary diagnosis. That is, a selected condition must be a CC or MCC diagnosis code that would, in the absence of the HAC payment provision, result in the assignment of a higher paying DRG.

The third criterion requires that a selected condition must be considered reasonably preventable through the application of evidence-based guidelines.

Guidelines developed by entities such as the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), professional organizations, and academic institutions were reviewed to evaluate whether guidelines are available that

hospitals should follow to prevent conditions from occurring in hospitals. The absence of prevention guidelines for many potential candidate conditions, including certain infectious conditions, limits the universe of candidate conditions.

In addition, the third criterion requires that a selected condition be considered reasonably preventable when the interventions in the guidelines are followed. The absence of evidence quantifying the extent to which application of evidence-based guidelines results in the prevention of certain conditions, including infectious conditions, also limits the universe of candidate conditions.

Selected HACs for 2009

After evaluating proposed candidate conditions against the statutory criteria and considering public comments received during FY 2007, FY 2008, and FY 2009 IPPS rulemaking, CMS and CDC experts selected 10 categories of conditions to which the HAC payment provision will apply beginning October 1, 2008. The HACs are more precisely defined by specific diagnosis codes (see Appendix E for specific codes).

| HACs - 10 Categories of Conditions |
|---|
| 1. Foreign Object Retained After Surgery |
| 2. Air Embolism |
| 3. Blood Incompatibility |
| 4. Pressure Ulcer Stages III & IV |
| 5. Falls and Trauma: - Fracture - Dislocation - Intracranial Injury - Crushing Injury - Burn - Electric Shock |
| 6. Catheter-Associated Urinary Tract Infection (UTI) |
| 7. Vascular Catheter-Associated Infection |
| 8. Manifestations of Poor Glycemic Control |
| 9a. Surgical Site Infection, Mediastinitis Following Coronary Artery Bypass Graft (CABG) |
| 9b. Surgical Site Infection Following Certain Orthopedic Procedures |
| 9c. Surgical Site Infection Following Bariatric Surgery for Obesity |
| 10. Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures |

Enhancements and Future Issues

Each year through IPPS rulemaking, CMS will consider refinements to the HAC list and potential candidate conditions. This might include the consideration of additional categories of conditions, expansion of existing categories, and reconsideration of

conditions that had previously been proposed but not selected. For example, stakeholders have suggested that water-borne pathogens be considered, that the surgical site infection category be expanded, and that ventilator-associated pneumonia and *Staphylococcus aureus* septicemia be reconsidered. The ability to select additional conditions will depend on the development of evidence-based guidelines such that when those guidelines are followed, the conditions can be considered reasonably preventable. In addition, having the POA indicator as a part of the Medicare claims data will help facilitate identification of additional candidate HACs.

Consumer groups and the media have suggested that methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* should be selected as HACs for the payment provision. Importantly, these infectious agents are directly addressed in part by the infectious conditions currently selected as HACs. For example, MRSA could be the etiologic agent for a vascular catheter-associated infection. However, the current coding for MRSA and *C. difficile* does not differentiate colonization from infection. As the diagnosis coding is refined, the ability to differentiate community from hospital-acquired infections improves, and evidence-based guidelines for the prevention of infectious agents are defined and enhanced, these infectious agents may be reconsidered as candidates for the HAC payment provision in future rounds of IPPS rulemaking.

Several means to make the HAC payment policy more precise could be considered in the future, including risk adjustment, implementation of a more sophisticated VBP model based on occurrence rates for conditions over time, and adoption of ICD-10. Rather than not paying any additional amount when a selected HAC occurs during hospitalization, payment reductions could be made proportional to the patient's or patient population's risk – the relative likelihood of acquiring a particular condition during hospitalization. This approach may recognize that medical history, co-morbidities, and severity of illness, among other factors, affect the expected occurrence of complications.

The application of a performance-based payment model that incorporates complication rates over time may be a more meaningful, actionable, and fair way to adjust a hospital's payments up or down based on the incidence of HACs (see discussion below in Section III.D.2, entitled, "Hospital Value-Based Purchasing Plan Report to Congress").

The adoption of ICD-10 would provide a better infrastructure for the HAC payment policy. Having more specific coding information would facilitate more precise identification of HACs. The adoption of ICD-10 has been proposed through rulemaking.

Collection of the POA indicator will provide important information, not only for Medicare payment, but also for enhancing public health. Researchers should be able to use POA data for risk adjustment of quality measurement data and to gain insights into the incidence of conditions in the community and in hospitals. The POA data can

be analyzed for only Medicare beneficiaries or can be combined with private sector or state POA data to support broader conclusions. In addition, POA data, including POA data about hospital-acquired infections, could inform publicly reported information to support better health care decision making by consumers and professionals.

C. Hospital Pay-for-Reporting

Another approach CMS has adopted as it transforms the Medicare program from a passive payer towards the goal of being an active purchaser of higher quality, more efficient health care is hospital pay-for-reporting.

This initiative is intended to equip consumers with quality of care information to make more informed decisions about their health care, while encouraging hospitals and clinicians to improve the quality of inpatient care provided to all patients. In December 2002, the HHS Secretary announced a partnership with several collaborators intended to promote hospital quality improvement and public reporting of hospital quality information. These collaborators included the American Hospital Association (AHA), the Federation of American Hospitals (FAH), the Association of American Medical Colleges (AAMC), the Joint Commission on Accreditation of Healthcare Organizations (now called The Joint Commission), the National Quality Forum (NQF), the American Medical Association (AMA), the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons (AARP), the American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), AHRQ, as well as CMS and others. In July 2003, CMS began the National Voluntary Hospital Reporting Initiative. This initiative is now known as the Hospital Quality Alliance (HQA): Improving Care through Information.

CMS established a “starter set” of 10 quality measures, used to gauge how well an entity provides care to its patients. Measures are based on scientific evidence and can reflect guidelines, standards of care, or practice parameters. A quality measure converts medical information from patient records into a rate or percentage that allows facilities to assess their performance.

This set includes measures addressing acute myocardial infarction, heart failure, and pneumonia, for voluntary reporting as of November 1, 2003. The 10 quality measures were endorsed by the NQF, a voluntary consensus standard-setting organization established to standardize health care quality measurement and reporting. In addition, this starter set is a subset of measures currently collected for The Joint Commission as part of its hospital inpatient certification program. CMS chose these 10 quality measures to collect data that would: (1) provide useful and valid information about hospital quality to the public; (2) provide hospitals with a sense of predictability about public reporting expectations; (3) begin to standardize data and data collection mechanisms; and (4) foster hospital quality improvement.

Hospitals submit quality data through the secure portion of the QualityNet Web site (formerly known as QualityNet Exchange) (www.QualityNet.org). Data from this

initiative are used to populate the Hospital Compare Website (see discussion in Section IV.B below).

Hospitals that did not submit data received a reduction of 0.4 percentage points to their update percentage increase (also known as the market basket update) for each of FYs 2005 through 2007, establishing an incentive for Inpatient Proposed Payment System (IPPS) hospitals to submit data on the specified 10 quality measures. The reduction to the update has subsequently increased from 0.4 to 2.0 percentage points for FY 2007 and beyond. For FY 2008, CMS required that hospitals submit data regarding 27 quality measures. The quality data collected includes a number of infection-related measures and encompasses the following conditions: acute myocardial infarction, heart failure, pneumonia, surgical care improvement, 30-day mortality rates for acute myocardial infarction and heart failure patients, and patients' experience of care through the HCAHPS patient survey.

CMS will collect a total of 42 quality measures for FY 2010, including: (1) Nine CMS-calculated AHRQ Patient Safety Indicators (PSIs) and Inpatient Quality Indicators (IQIs) that have been endorsed by the NQF; (2) another NQF endorsed measure, Participation in a Systematic Database for Cardiac Surgery; and (3) a heart failure readmission measure.

Specific infection-related measures include:

- Timing of receipt of initial antibiotic following hospital arrival
- Blood culture performed before first antibiotic received in hospital
- Appropriate initial antibiotic selection
- Prophylactic antibiotic received within one hour prior to surgical incision
- Prophylactic antibiotics discontinued within 24 hours after surgery end time
- Surgical Care Improvement Project (SCIP) Infection 2: Prophylactic antibiotic selection for surgical patients
- SCIP Infection 4: Cardiac surgery patients with controlled 6AM postoperative serum glucose
- SCIP Infection 6: Surgery patients with appropriate hair removal

CMS anticipates adopting additional readmission measures as discussed in the FY 2009 IPPS final rule, pending endorsement by the NQF.

The maintenance of measure specifications occurs through publication of the Specifications Manual. Thus, measure selection occurs through the rulemaking process; whereas the maintenance of the technical specifications for the selected measures occurs through a sub-regulatory process so as to best maintain the specifications consistent with current science and consensus. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet web site at www.QualityNet.org.

D. Demonstration Projects

The Medicare Program has a long and successful history of developing program initiatives through its demonstration authority. At any given time, CMS has over three-dozen demonstrations in its portfolio, including demonstrations under development, demonstrations in operation, and demonstrations that are in a close-out phase. The development and implementation of these demonstrations frequently provide the agency practical lessons on policy tradeoffs and objectives, details related to operations of a specific pilot program, and unanticipated issues related to how to recruit and engage demonstration participants.

In addition to these practical design and implementation issues, formal evaluations play a critical part of any demonstration. CMS' Office of Research, Development, and Implementation conducts full evaluations of each demonstration project with help from experts from the research community. Evaluations are carefully developed, often using randomly-assigned control groups and other sophisticated evaluation techniques, to report the results of the demonstrations to CMS and other executive branch leadership, the Congress, and the public.

CMS currently has several demonstration projects that are designed to test methods to improve the value of healthcare. One of the most important of these is the Premier Hospital Quality Incentive Demonstration, which includes 250 hospitals in 38 states in collaboration with Premier, Inc., which operates a large quality measurement and improvement operation. That demonstration started in October 2003, and has documented substantial improvements in the quality of inpatient care. The demonstration is measuring and providing bonus incentives for improving quality of care in five clinical areas: acute myocardial infarction, pneumonia, heart failure, coronary artery bypass graft, and hip and knee replacement. In the initial three years of operations, the demonstration hospitals have improved their quality of care in five clinical areas by an average of 16 percentage points.

CMS has extended the demonstration for a second three-year period. CMS added new quality measures for testing, including all of the Surgical Care Improvement Project (SCIP) measures. These measures have just recently been added to the demonstration, so it is too early to determine the extent to which these new measures have shown improvement.

In developing demonstrations, CMS uses the most recent available quality measures wherever applicable, including the SCIP measures, which are included in the two related gainsharing demonstrations. These demonstrations are designed to study whether incentives for collaborative arrangements between hospitals and physicians can improve the quality and efficiency of care provided to Medicare beneficiaries. The demonstrations are intended to provide for parallel incentives for hospitals and physicians, thus improving coordination and quality. Efficiencies will be measured in internal hospital costs, and if the hospitals are successful in reducing their costs, they may share savings with physicians and with clinical staff. Examples of greater

efficiencies include providing diagnoses faster and thus reducing length of stay, improving the turnaround in operating rooms, reducing the use of redundant tests, and the use of innovative products to improve treatment efficiency. CMS is carefully tracking quality of care in participating hospitals to assure that the demonstration results in improved care, and not in any reduced quality. Among the measures of quality are SCIP measures including the use of prophylactic antibiotics before surgical incisions, the proper selection of antibiotics, proper surgical preparation to avoid infections, and discontinuation of the antibiotics on schedule to reduce antibiotic resistant bacteria strains.

The SCIP measures are also included in a key demonstration that is intended to improve inpatient quality of care, the Acute Care Episode (ACE) Demonstration. In this demonstration, scheduled for implementation in early 2009, Medicare will pay up to 15 hospitals in Texas, Oklahoma, Colorado, and New Mexico a “global fee” for cardiac and orthopedic procedures. The global fee is a bundled payment for both hospital and physician costs, including the surgeon, any consultants, radiologists, anesthesiologists, or other physicians included in the care of the patient.

The participating hospitals and physicians will be permitted to use gain-sharing to improve incentives for collaboration. This demonstration is intended to improve internal hospital cost efficiency and quality of care, reduce costs for Medicare, and improve transparency of information for beneficiaries. Quality will be measured through a series of reported process and outcome measures, including several that focus on surgical infections such as selection and administration of antibiotics and deep sternal wound infection rate.

Thus, in three important Medicare demonstrations that involve inpatient costs and efficiency, CMS has measured the quality of care using available quality measures, and that these measures will be monitored on a regular basis to track progress toward improving quality. If any demonstration hospital were found to be unable to maintain high levels of quality, that participating hospital could be removed from the applicable demonstration. The measurement and evaluation of hospital-acquired infections are an important part of this evaluation, and the Medicare demonstrations program will continue to include HAI measures, as they are developed, standardized, and available for use in the demonstration projects.

E. Hospital Value-Based Purchasing Plan Report to Congress

Introduction

On November 21, 2007, CMS submitted a Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program (the Plan).³ The Plan would build on the current hospital pay-for-reporting program discussed above and establishes performance-based Medicare hospital payment. Under value-based purchasing (VBP), a portion of hospital payment would be contingent on actual

³ www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf

performance, rather than simply on a hospital's reporting of measurement data. The VBP performance measures would include infection rates.

Hospital VBP would provide powerful incentives – both financial and non-financial – for discouraging hospital-associated infections. Payments to higher performing hospitals would be larger than those for lower performing hospitals, providing financial incentives to drive improvement. Public reporting of performance on Medicare's Hospital Compare website, (discussed below in Section IV) would provide non-financial incentives to encourage hospital performance improvement.

Extensive public input was sought during each phase of plan development. Two Listening Sessions to receive individual input from organizations and individuals were held: the first to discuss the key issues in hospital performance-based payment and a second to discuss design options for the Plan. The Listening Sessions elicited over 100 comments. Comments were also sought during FY 2007, FY 2008, and FY 2009 IPPS rulemaking. In addition, on several occasions, CMS leaders met with leaders from national hospital organizations to discuss issues related to Plan development.

Hospital VBP Performance Assessment Model and Incentive Payments

The performance assessment model is the methodology that would be used for scoring hospital performance on specific measures. Those aggregate scores would then be used to determine an incentive payment. The model evaluates a hospital's performance on each measure based on the highest of either an attainment score or an improvement score. The improvement score would be determined by comparing the hospital's current score with its baseline performance.

A hospital's performance on individual measures would be summed within each measurement domain – such as process of care, outcomes, or patient experience – and then the domains would be weighted and summed to yield the hospital's total performance score. Using an exchange function, the hospital's total performance score would be translated into an incentive payment. The source of the incentive payment would be a percentage of the hospital's base operating DRG payments. Essentially, hospitals would have to earn back a portion of their Medicare payments by performing at a high level or improving their performance.

Hospital VBP Measures

Measures are the foundation of performance-based payment. To qualify for the incentive payment under the Plan, a hospital must report on all measures relevant to its service mix. Measures of various aspects of healthcare quality, such as patient safety, process of care, outcomes, patient experience, efficiency, and care coordination, would be added over time. A subset of the current hospital pay-for-reporting measures would be used for initial implementation, including the current infectious-condition measures related to pneumonia and surgical infection prevention. As measures related to infectious conditions emerge from development and testing, they would be adopted for the VBP financial incentives and public reporting.

Other Issues in the Hospital VBP Plan

The Hospital VBP Plan addresses a number of other issues related to the design and implementation of hospital performance-based payment. The current infrastructure for reporting hospital data would be improved through streamlining the submission process, allowing resubmissions, improving feedback reports, enhancing user support, and strengthening data validation. The Hospital Compare website could continue to serve as the platform for public display of performance results. Given the relative newness of performance-based payment, mechanisms for real-time monitoring and in-depth evaluation would be necessary for timely corrective action of unintended consequences and future enhancements.

Enhancements and Future Issues

CMS continues to refine the Hospital VBP Plan and to test the financial impact that the Plan would have on various types of hospitals if it were implemented. Preliminary tests show that the Plan would reward hospitals that achieve high levels of attainment or improvement, without unintended re-distributional effects.

In implementing the Hospital VBP Plan, the measures for the financial incentive and public reporting would continue to evolve. A patient safety domain of measurement could be expanded over time to include measures addressing the priority infections identified.

F. Recommendations and Action Plan

CMS currently has the statutory authority to adjust hospital MS-DRG payments for selected conditions under the HAC payment provision. CMS has selected catheter-associated urinary tract infection, vascular-catheter associated infection, and certain surgical site infections for non-payment under the HAC provision when those infections are acquired during hospitalization.

Other infections, like ventilator-associated infections, methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, and other surgical site infections may be reconsidered as candidates for the HAC payment policy during future rounds of rulemaking; however, the ability to select additional conditions will depend on the development of evidence-based guidelines and on published literature supporting the conclusion that when the guidelines are followed, the conditions can be considered reasonably preventable.

CMS also currently has the statutory authority to collect and publicly report hospital quality data under the RHQDAPU program. The RHQDAPU program measures compliance with an increasing number of infection prevention and control best practices, including measures developed by the Surgical Care Improvement Project.

Adoption of additional measures occurs through rulemaking, which occurs annually with a proposed rule published in the Federal Register in the spring and a final rule published by August.

CMS has used the experience gained through implementing the HAC payment provision, through the RHQDAPU measurement and public reporting program, and through the various performance-based payment demonstration projects, to inform the development of the Hospital VBP Plan. CMS believes that the Hospital VBP Plan, if the agency had that statutory authority to implement, would be a more sophisticated approach to value-based purchasing than the current HAC and pay-for-reporting approaches. Risk-adjusted rates of infection prevention interventions and outcomes over time for infections like ventilator-associated pneumonia, MRSA, or *C. difficile* could be included to enhance a patient safety domain of measurement, which would count toward determination of a hospital's VBP incentive payment for all DRGs.

Thus, the infection prevention and outcomes measures in the patient safety domain could become a subset of the "rollup measure" or total performance score of the hospital VBP performance assessment model. Scores for the individual infection prevention and outcomes measures, for aggregated infection measures, and for the patient safety domain could be posted on the Hospital Compare website, along with the scores for the other domains and the total performance score, and could serve as one type of "scorecard" for infection prevention and outcomes.

Recommendations on how the Hospital VBP Plan methodology could incorporate measures of infection prevention and outcomes:

- Individual measures of infection prevention and outcomes, specified elsewhere in this report, could be scored for hospitals as part of performance assessment.
- Individual infection measure scores could be aggregated into a rollup infection measure for hospitals.
- Individual infection measure scores or a rollup infection measure could be aggregated into a roll up patient safety domain, which could be included in hospitals' total performance scores. Thus, hospitals' financial incentives would depend, in part, on their performance on measures of infection prevention and outcomes.
- Scores for individual measures, roll up infection measures, and the roll up patient safety domain could be reported on Hospital Compare as an infection scorecard for hospitals.

However, even if the Hospital VBP Plan were implemented, elements of the HAC provision and the RHQDAPU program would ideally be retained to serve specific purposes. For example, the HAC payment provision could be better suited for conditions with a very low incidence that cannot be accurately and reliably measured

by rates, and the RHQDAPU program's pay-for-reporting approach could be useful for collecting data on measures that are being tested for VBP or that are topped out and no longer provide meaningful differentiation in performance for VBP payment incentives.

The President's FY 2009 Budget proposed the Hospital VBP Plan as a way to enhance the quality and value of Medicare services. In the interim, CMS will continue to consider candidate HACs through rulemaking and will pursue evaluation of promising value-based purchasing strategies through demonstration projects.

IV. Transparency and Associated Incentives

A. Introduction

Transparency is a broad-scale initiative intended to equip consumers with quality of care information to make informed decisions about their health care, while encouraging institutions and clinicians to improve the quality of care provided to all patients. Transparency in healthcare facilitates improvement of performance, efficiency, and quality by providing facilities and physicians with the additional information necessary for benchmarking.

Public reporting enhances accountability in healthcare by increasing the transparency of quality data. Public reporting is designed to create both "indirect" financial and non-financial incentives to improve quality of care. Indirect financial incentives result when public reporting drives patients' choices and, therefore, market share. Non-financial incentives include publicizing performance, reputation, competition, motivation, accountability, and public recognition. Providing reliable quality and cost information empowers not only patients' choices, but also the choices of stakeholders within local and regional communities, as well as nationally. Professionals are more likely to want to join the staffs of high performing hospitals. Choice leads to incentives at all levels and motivates the entire system; improvements take place as providers compete.

B. Hospital Compare

Hospital Compare (www.hospitalcompare.hhs.gov) is a consumer-oriented website that provides information on how well hospitals provide care to their patients with certain medical conditions, including care related to the prevention of infections. Hospital Compare publicly reports hospital performance data in a consistent, unified manner to ensure public availability of credible information about the care delivered in the nation's hospitals.

The effort to publicly report various processes of care and outcome measures furthers the goal to improve the quality and transparency of hospital care by giving the public

and healthcare professionals better access to important hospital data. These quality measures are meant to be one way to see how well a hospital is caring for its patients.

By making this information available, CMS is meeting two of the Secretary's four cornerstones for Value-Driven Health Care – to measure and publish quality and price information. Hospital Compare allows consumers to see how hospitals are delivering care to their patients through nationally standardized process of care and outcome measures and cost information for individual hospitals. This information helps educate consumers who are selecting a hospital.

CMS launched the Hospital Compare tool on March 31, 2005. The measures currently reported on Hospital Compare include 10 starter measures and additional measures that many hospitals also voluntarily report to receive their full payment updates (see Appendix F). These measures represent agreement among CMS, the hospital industry, and public sector stakeholders such as The Joint Commission, NQF, and AHRQ. A number of the measures are related to infections: there are three measures related to the prevention of surgical infections, seven measures related to pneumonia care, and one measure related to pneumonia outcomes.

Recently, ten measures from a standardized survey of patient perspectives of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), have also been added to the Hospital Compare site. Public reporting of standardized measures on patients' perspectives of the quality of hospital care encourages consumers and their physicians to discuss and make more informed decisions on how to get the best hospital care, as well as increases the public accountability of hospitals.

The transparency provided by the Hospital Compare tool provides incentives for the entire hospital system. The tool is not only a valuable information resource for patients but also could enhance a hospital's reputation in the community. A hospital performing well on the Hospital Compare site could provide a community reputation that attracts patients, physicians, and staff.

C. Recommendations and Action Plan

Each year, CMS will continue adding additional measures to Hospital Compare. These enhancements are part of HHS' ongoing commitment to increased healthcare transparency. CMS is adding 13 new measures for the FY 2010 program, and retiring one existing measure. The inclusion of these additional measures will encourage hospitals to take steps to make care safer for patients.

As measures are developed for hospital-associated infections related to catheter-associated urinary tract infections, vascular-catheter associated infections, ventilator-associated pneumonia, surgical site infections, methicillin-resistant *Staphylococcus aureus*, and *Clostridium difficile*, they may be added to the Hospital Compare website.

The addition of hospital-associated infection measures to Hospital Compare could increase awareness and educate consumers as well as continue to hold hospitals and other providers accountable for providing better more efficient care.

V. Related Initiatives Addressing Healthcare-Associated Infections

A. Introduction

CMS has undertaken a number of other Medicare and Medicaid initiatives to combat healthcare-associated infections. Within the Medicare program, the Quality Improvement Organizations (QIOs) provide direct provider support for reducing infections. Medicare Part C is applying the Part A hospital-acquired conditions payment policy to Medicare Advantage organizations, which also have quality improvement program requirements that include the prevention and control of infections. The Medicaid program is encouraging States to adopt the Medicare hospital-acquired conditions payment policy and is funding Transformation Grants that include addressing central line infections for premature infants in the Neonatal Intensive Care Unit (NICU).

B. Quality Improvement Organizations

Introduction

The statutory mission of the Quality Improvement Organization (QIO) program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The QIO Program is a network of organizations staffed with physicians, nurses, technicians, and statisticians – experts in healthcare quality – with each QIO responsible for a U.S. state, territory, or the District of Columbia. Each of the 53 QIOs is governed by a performance-based cost reimbursement contract. The current contract, (the 9th Scope of Work (SOW), which continues for three years beginning August 2008) focuses on four themes: Beneficiary Protection, Care Transitions, Patient Safety, and Prevention. There are also three cross-cutting themes: Reducing Health Care Disparities, Promoting Use of Health Information Technology, and Value-Driven Health Care and a comprehensive set of tasks, roles and responsibilities, progress measures, and an evaluation design.

The following discussion expands on the Patient Safety and Prevention themes, which are more relevant to the healthcare-associated infections focus of this report.

Patient Safety

Patient Safety efforts will reduce patient harm using proven interventions in areas with a record of QIO success in helping to improve safety. This work will define improvement in patient safety as the reduction or elimination of patient harm that is more likely a result of the patient's interaction with the healthcare system than an attendant disease process. Work toward these goals will by definition increase the

value of healthcare services as it produces higher quality care for Medicare beneficiaries.

QIO activities for the Patient Safety Theme will focus on five topics: improving inpatient surgical safety, heart failure, reducing rates of nosocomial MRSA infections, improving drug safety, and reducing rates of pressure ulcers and physical restraints in nursing homes as well as pressure ulcers in hospitals. Additionally, nursing homes that have difficulty meeting the CMS survey and certification requirements will be given the opportunity to work with QIOs to assess the areas for improvement and to work on their pressure ulcer and physical restraint rates. QIOs will work with providers to achieve the following: 23,610 fewer restraints, 43,303 fewer patients with pressure ulcers in nursing homes and hospitals, 7,875 fewer MRSA infections, and 14,252 fewer postoperative deaths due to surgical site infection, venous thromboembolic events, or perioperative myocardial infarction.

In CMS' efforts to improve quality and avoid unnecessary costs to the Medicare Trust Fund, the Office of Clinical Standards and Quality (OCSQ), as part of the QIO 9th SOW's Patient Safety Theme, has formed an interagency collaboration with CDC and AHRQ to combat hospital-acquired MRSA. Over the past several decades, the incidence of MRSA infections has grown exponentially. In 1974, MRSA infections accounted for only two percent of the total number of staphylococcus infections; in 1995 it was 22%; in 2004 it was 63%. This rate comes with a mean per patient cost of \$35,367 that is directly attributable to MRSA infections.

The new 9th SOW contract, which began on August 1, 2008, creates an opportunity for hospitals to choose to report on MRSA under the CDC's NHSN Multidrug-Resistant Organism (MDRO) Module and to work with QIOs to reduce infection and transmission rates attributable to MRSA. CDC oversees the NHSN and will soon be launching the MDRO Module, which tracks MRSA infections. All hospitals are encouraged to consider reporting through the MDRO module. Hospitals choosing to participate in the MDRO module will undergo on-line training provided by CDC for the NHSN and the MDRO Module. Hospitals working with the QIOs will receive additional training based on proven effective practices for reducing healthcare-associated MRSA infections and TeamSTEPPS. TeamSTEPPS is a teamwork system which offers a powerful solution to improving collaboration and communications within institutions. Teamwork has been found to be one of the key initiatives within patient safety that can transform the culture within healthcare.

Prevention

Prevention efforts will emphasize evidence-based and cost-effective care proven to prevent and/or slow the progression of disease. Work toward these goals will affect healthcare programs, products, policies, practices, community norms, and linkages and will produce higher quality of care for Medicare beneficiaries and significant cost savings. Over time, as disease is mitigated and its progression slowed through preventive measures such as early testing, immunization, and effective and timely intervention, the nation will see a healthier Medicare population emerge. This

downstream impact will be most evident in the reduction of chronic kidney disease (CKD) and decrease in the rate of progression to kidney failure.

C. Medicare Advantage Efforts

New Reporting Requirements for Medicare Advantage Organizations

As part of the proposed Medicare Part C reporting requirements effective January 1, 2009, CMS will collect a set of measures that involve hospital-acquired conditions. Some of these measures involve infections, including: vascular catheter-associated infection; catheter-associated urinary tract infection (UTI); surgical site infection, mediastinitis, after coronary artery bypass graft (CABG); surgical site infection following certain orthopedic procedures; and surgical site infection following bariatric surgery for obesity. These data will be used in developing and reporting performance metrics for Medicare Advantage (MA) organizations.

CMS will be issuing guidance to MA consistent with original Medicare rules effective October 1, 2008 to not cover specified preventable medical errors that occur at non-contracting hospitals (see discussion in Section III.B above). CMS will also be updating the "MA Payment Guide for Out of Network Payments" to reflect this information for all MA plans.

Medicare Advantage Quality of Care Requirements

The MA quality framework, including quality improvement programs (QIPs), are described in the MA regulations, which currently require MA coordinated care plans to:

- 1) Have QIPs.
- 2) Initiate annual QI projects and report results to CMS on these projects when they submit materials for their routine CMS audits.
- 3) Have a chronic care improvement program.
- 4) Report on annual activity of their Chronic Care Improvement Program when they submit materials for their routine CMS audits; and
- 5) Report standardized performance measures specified by CMS annually. These standardized performance measures include: HEDIS, CAHPS, and HOS. HEDIS covers measures related to effectiveness of care, access/availability of care, and use of services; CAHPS measures experiences with the care received through the health plan; and HOS measures changes in physical and mental health status.

Under the MA provider selection and credentialing requirements, MA plans are required to contract with providers who meet the credentialing requirements specified in the MA regulations. Included is a requirement that providers must be State licensed and in compliance with all applicable state and federal requirements.

Under the recent Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), beginning in 2011, each MA Private Fee-for-Service (PFFS) and Medicare Savings Account (MSA) plan must have an ongoing QIP that meets the regulatory requirements. CMS is currently developing regulations to implement these new MIPAA quality requirements for PFFS and MSA plans. For 2010, MSA and PFFS plan QI reporting will only apply with respect to administrative claims data.

D. State Medicaid Program Efforts

The implementation of Medicare's hospital-acquired conditions (HACs) payment policy (see discussion in Section III.B above) left many State Medicaid Agencies wondering whether healthcare providers serving dually-eligible Medicaid and Medicare patients would simply attempt to pass through unpaid Medicare bills to Medicaid as a secondary payer. Such action would effectively shift costs to States and, even more seriously, undermine any deterrent effect that the Medicare HAC payment policy would otherwise have.

Consequently, on July 31, 2008, CMS issued a State Medicaid Directors' Letter (SMD). The SMD (#08-004) invited States to submit State Plan Amendments (SPAs) to CMS to conform State Medicaid payment policy to the Medicare HAC payment policy. The letter offered States the option to do nothing, to conform Medicaid payment policy to the Medicare HAC non-payment policy, or to establish a more ambitious "never events" policy that might add any of the 28 "never events" defined by the NQF or other health organization (e.g., CDC) to the Medicare HACs. Some of the "never events" are related to infections, like death or disability associated with the use of contaminated drugs, devices, or biologics; severe pressure ulcers; and burns. The letter encouraged States to consider the entire Medicaid population (not just dual eligibles) in formulating this State payment policy, to clearly link payment with performance.

About 20 of the States had already expressed interest in a "never event" policy and most had expected to use all or some of the 28 NQF "never events" as the basis for their Medicaid payment policies. With the issuance of the new SMD, CMS expects that the majority of States will move to align their Medicaid payment policies with the Medicare HAC policy. Given that many of the HACs deal with hospital-acquired infections, this alignment of Medicare and Medicaid payment policy will send a strong, consistent message to hospitals that federal and state payers expect them to strengthen their infection control programs and prevent all avoidable hospital-acquired infections.

The Neonatal Outcomes Project is another Medicaid infection prevention project that involves the creation and testing of a Protocol for the Prevention and Handling of Premature Births. The project commenced in 2006 and, among other interventions, addresses proper infection control practices in the NICU. At this point, three states have been selected for CMS Transformation Grants to pilot certain of the interventions. These interventions are evidence-based and have been shown to be

effective, and the Grants are intended to spread the promising practices into the wider neonatal community to reduce variability in outcomes and improve overall mortality and morbidity statistics for prematurity throughout the nation.

Ohio, which has the first operational Transformation Grant, has as one of its two objectives the infection control intervention, which addresses central line infections in the NICU. Central line infections are a significant issue in NICUs in Ohio and across the nation, but there is an established protocol to reduce these infections to a fraction of their present level. This protocol was first tested for adults by the Institute for Healthcare Improvement (IHI) in its successful 100,000 Lives campaign. Subsequently, the Perinatal Quality Improvement Panel of California modified the protocol for neonates and, in 2004, published its results (Wirtschafter, NeoReviews, 2004). These results indicated that the neonatal protocol, when properly applied, reduced central line infections to less than half of the previous rate before use of the protocol.

It is expected that the results of these Transformation Grants will demonstrate the effectiveness of these improved infection control techniques for premature infants in the NICU and justify a national effort to introduce these evidence-based methods into routine perinatal practice.

VI. Conclusion

CMS, working with other HHS agencies and various national and local partners, has a number of initiatives and programs to regulate and track HAI infections; and compliance with these regulations and promotion of the quality based improvement practices used by CMS in concert with its partners, will improve the public's health. Increasingly, these efforts also include more direct sources of information for providers and patients that should influence choices that help diminish and prevent healthcare-associated infections.